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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,536

07/19/2006

Herve Tettelin

PP019195.005/CHIRP024

4756

27476

7590

11/20/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

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EXAMINER

OGUNBIYI, OLUWATOSIN A

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,536	<b>Applicant(s)</b> TETTELIN ET AL.	
	<b>Examiner</b> Oluwatosin Ogunbiyi	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-13 are pending in the application.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9 and 12-13, drawn to an immunogenic composition comprising a combination of GBS polypeptides.

Group II, claim(s) 10 and 11, drawn to a polynucleotide sequence, or a fragment comprising at least 10 contiguous polynucleotides, selected from the sequences set forth on Tables 13-31 and 40-89.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I and II is an immunogenic composition comprising a combination of GBS polypeptides said combination consisting of two, three, four or five

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polypeptides; and a polynucleotide encoding a GBS polypeptide, respectively. This technical feature of Group I is anticipated by Vallejo et al. Journal of Immunology, 2000, 165:419-425. Vallejo et al teaches an immunogenic composition i.e. a Group B Streptococcus (GBS) strain COH1. Said composition inherently comprises a combination consisting of two or three or four or five polypeptides each encoded by a GBS polynucleotide which is homologous to a polynucleotide sequence of Group A *Streptococcus* (GAS) or *Streptococcus pneumoniae* or both. Thus, Group I lacks unity with Group II, because the technical feature of Group I is anticipated by the art and therefore not “special” within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

### ***Species election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows:

Group I: Select from the following

- A. Combination of GBS polypeptides encoded by a GBS polynucleotide sequence which is homologous to a polynucleotide sequence of both GAS and *S. pneumoniae*. If this group is elected, further elect a single combination of 2 or 3 or 4 or 5 polypeptides.
- B. Combination of polypeptides encoded by a GBS polynucleotide homologous to polynucleotide sequence of GAS but not with *S. pneumoniae*. If this group is elected, further elect a single combination of 2 or 3 or 4 or 5 polypeptides.

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- C. Combination of polypeptides encoded by a GBS polynucleotide homologous to a polynucleotide sequence of *S. pneumoniae* but not with GAS. If this group is elected, further elect a single combination of 2 or 3 or 4 or 5 polypeptides.

Group II:

A single polynucleotide sequence selected from those listed in claim 10.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the technical feature of each of the species of Group I is anticipated by the art as set forth above. Further, the species of polynucleotide lack the same or corresponding special technical features for the following reasons: the polynucleotides lack a common structure.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is (571)272-9939. The examiner can normally be reached on M-F 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shannon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/  
Examiner, Art Unit 1645

/Patricia A. Duffy/  
Primary Examiner, Art Unit 1645